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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., **Plaintiff,** **v.** **DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 8,298,576 ("the '576 patent"), 8,298,580 ("the '580 patent"), 8,663,683 ("the '683 patent"), 8,877,248 ("the '248

patent"), 8,889,191 ("the '191 patent"), 8,992,989 ("the '989 patent"), 9,549,940 ("the '940 patent"), 9,555,004 ("the '004 patent"), 9,622,983 ("the '983 patent"), and 10,314,790 ("the '790 patent") attached hereto as Exhibits A–J (collectively, "the patents-in-suit").

THE PARTIES

2. Plaintiff Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

3. Upon information and belief, Defendant Dr. Reddy's Laboratories, Ltd. is a corporation operating and existing under the laws of India, with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500 034, India.

4. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 107 College Road East, Princeton, NJ 08540. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a wholly-owned subsidiary, directly or indirectly, of Dr. Reddy's Laboratories, Ltd. Upon information and belief, Dr. Reddy's Laboratories, Inc. acts at the direction of, under the control of, and for the direct benefit of Dr. Reddy's Laboratories, Ltd. and is controlled and/or dominated by Dr. Reddy's Laboratories, Ltd.

5. Upon information and belief, DRL filed Abbreviated New Drug Application No. 217231 ("the DRL ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of generic topiramate extended-release capsules, containing 25 mg, 50 mg, 100 mg, and 200 mg of topiramate ("DRL ANDA Products").

6. Upon information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are acting cooperatively with respect to the DRL ANDA.

7. Upon information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. collaborate to develop, manufacture, import, market, and distribute, and/or sell pharmaceutical products, including generic drug products (e.g., ciprofloxacin dexamethasone otic suspension, diclofenac sodium topical gel, sapropterin dihydrochloride tablets, and colchicine tablets)[1] that will be manufactured and sold, pursuant to an ANDA, throughout the United States, including throughout the State of New Jersey.

8. Upon information and belief, Defendants and/or their affiliates manufacture and/or direct the manufacture of generic pharmaceutical products for which DRL is the named ANDA applicant. Upon information and belief, Defendants each, directly or indirectly, derive substantial revenue from the sales of such generic pharmaceutical products.

9. Upon information and belief, DRL will market the DRL ANDA Products throughout the United States, including in New Jersey, upon approval of the DRL ANDA.

10. On or about June 9, 2022, DRL sent a letter purportedly pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 regarding the DRL ANDA Products and the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents (the "June 9 Notice Letter") to Supernus at 9715 Key West Avenue, Rockville, Maryland 20850.

11. The June 9 Notice Letter was signed by Anjum Swaroop, the Vice President, Intellectual Property at Dr. Reddy's Laboratories, Inc. and the authorized representative for DRL.

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[1] *See* Dr. Reddy's Laboratories, Ltd.'s Annual Report 2020-21 at 45, https://www.drreddys.com/media/1003010/drl-annual-report-fy2021.pdf (last visited July 22, 2022).

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. This Court has personal jurisdiction over Defendants under: (i) Fed. R. Civ. P. 4(k)(1) and N.J. Ct. R. 4:4-4; and/or (ii) Fed. R. Civ. P. 4(k)(2).

14. Upon information and belief, Defendants have purposefully availed themselves of the privilege of doing business in the State of New Jersey by continuously and systematically placing goods in the stream of commerce for distribution and sale throughout the United States, including the State of New Jersey. For example, upon information and belief, DRL states that the United States is one of DRL's "principal markets."[2] Regarding its U.S. business, DRL's Annual Report 2020-2021 states that the company "filed 20 new Abbreviated New Drug Applications (ANDAs) and one New Drug Application (NDA) under the section 505(b)(2) with the US Food and Drug Administration (USFDA)."[3] DRL's Annual Report 2020-2021 also states that "[a]s on [sic] March 31, 2021, [DRL] had 95 generic filings pending approval from the USFDA" and "[t]hese comprise 92 ANDAs and three New Drug Applications (NDAs) filed under the Section 505(b)(2) route of the US Federal Food, Drug and Cosmetics Act."[4]

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[2] Dr. Reddy's Laboratories, Ltd.'s Annual Report 2020-21 at 109, https://www.drreddys.com/media/1003010/drl-annual-report-fy2021.pdf (last visited July 22, 2022).

[3] Dr. Reddy's Laboratories, Ltd.'s Annual Report 2020-21 at 42, https://www.drreddys.com/media/1003010/drl-annual-report-fy2021.pdf (last visited July 22, 2022).

[4] Dr. Reddy's Laboratories, Ltd.'s Annual Report 2020-21 at 42, https://www.drreddys.com/media/1003010/drl-annual-report-fy2021.pdf (last visited July 22, 2022).

15. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey, and importing generic pharmaceutical products into the United States, including throughout the State of New Jersey; (ii) in concert with and/or through its various subsidiaries, including Defendant Dr. Reddy's Laboratories, Inc., the preparation, submission, and filing of Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) in concert with and/or through its various subsidiaries, including Defendant Dr. Reddy's Laboratories, Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

16. Upon information and belief, Dr. Reddy's Laboratories, Inc. is in the business of, *inter alia*: (i) developing, marketing, distributing, and/or selling generic pharmaceutical products throughout the United States, including throughout the State of New Jersey; (ii) in concert with and/or through its parent, including Defendant Dr. Reddy's Laboratories, Ltd. and various subsidiaries, the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) alone or in concert with and/or through its parent, including Defendant Dr. Reddy's Laboratories, Ltd. and various subsidiaries, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

17. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc. at least because, upon information and belief: (i) Dr. Reddy's Laboratories, Inc. maintains a principal place of business in New Jersey located at 107 College Road East, Princeton, NJ 08540; (ii) Dr.

Reddy's Laboratories, Inc. is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) Dr. Reddy's Laboratories, Inc., together with its parent Dr. Reddy's Laboratories, Ltd., is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) Dr. Reddy's Laboratories, Inc., together with its parent Dr. Reddy's Laboratories, Ltd., has committed, induced, and/or contributed to acts of patent infringement in New Jersey; and (v) Dr. Reddy's Laboratories, Inc. has previously submitted to the jurisdiction of this Court, has availed itself of New Jersey's legal protections in prior litigations, and previously consented to personal jurisdiction and venue in this Judicial District.[5]

18. Upon information and belief, Dr. Reddy's Laboratories, Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0100518911.[6] Upon information and belief, Dr. Reddy's Laboratories, Inc. is registered with the State of New Jersey's Department of Health as a drug and medical device "manufacturer and wholesale[r]" with Registration Number

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[5] This Court also has personal jurisdiction over Defendants because Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have previously submitted to the jurisdiction of this Court and have previously availed themselves of this Court by initiating lawsuits and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Dr. Reddy's Labs. Inc. v. Amarin Pharma, Inc.*, No. 21-10309 (D.N.J. Apr. 27, 2021), ECF No. 1 (showing that DRL filed an action under the Sherman Act in New Jersey); *Celgene Corp. v. Dr. Reddy's Labs., Ltd.*, No. 21-2111 (D.N.J. Apr. 23, 2021), ECF No. 10 (showing that DRL filed a counterclaim and did not contest personal jurisdiction); *Horizon Pharma, Inc. v. Dr. Reddy's Labs., Ltd.*, No. 15-3324 (D.N.J. Feb. 19, 2016), ECF No. 28 (showing that DRL admitted to personal jurisdiction).

[6] New Jersey's Division of Revenue and Enterprise Services Website, https://www.njportal.com/DOR/BusinessNameSearch/Search/BusinessName (search business name field for "Dr. Reddy's Laboratories") (last visited July 22, 2022).

5002312.[7] Dr. Reddy's Laboratories, Inc. has, therefore, purposefully availed itself of the rights, benefits, and privileges of New Jersey's laws.

19. Upon information and belief, DRL derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

20. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. at least because, upon information and belief: (i) Dr. Reddy's Laboratories, Ltd. has purposefully directed its activities and the activities of Dr. Reddy's Laboratories, Inc. at residents and corporate entities within the State of New Jersey; (ii) the claims set forth herein against Dr. Reddy's Laboratories, Ltd. arise out of or relate to those activities; (iii) Dr. Reddy's Laboratories, Ltd.'s contacts with the State of New Jersey (direct and indirect) are continuous and systematic; (iv) it is reasonable and fair for this Court to exercise personal jurisdiction over Dr. Reddy's Laboratories, Ltd.; and (v) Dr. Reddy's Laboratories, Ltd. has previously submitted to the jurisdiction of this Court, has availed itself of New Jersey's legal protections in prior litigations, and previously consented to personal jurisdiction and venue in this Judicial District.[8]

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[7] New Jersey Department of Health Website, https://healthapps.state.nj.us/fooddrug/fdList.aspx (search company name field for "Dr. Reddy's Laboratories, Inc.") (last visited July 22, 2022).

[8] This Court also has personal jurisdiction over Defendants because Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have previously submitted to the jurisdiction of this Court and have previously availed themselves of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Celgene Corp. v. Dr. Reddy's Labs., Ltd.*, No. 21-2111 (D.N.J. Apr. 23, 2021), ECF No. 10 (showing that DRL filed a counterclaim and did not contest personal jurisdiction); *Horizon Pharma, Inc. v. Dr. Reddy's Labs., Ltd.*, No. 15-3324 (D.N.J. Feb. 19, 2016), ECF No. 28 (showing that DRL admitted to personal jurisdiction).

21. Upon information and belief, the tortious acts of DRL of (i) preparing and filing the DRL ANDA with a paragraph IV certification to the patents-in-suit for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products before the expiration of the patents-in-suit, and (ii) directing notice of its ANDA submission to Supernus, are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, offer to sell, and/or sale of the DRL ANDA Products by Defendants before the expiration of the patents-in-suit throughout the United States, including in this Judicial District. Because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, DRL should reasonably anticipate being sued in New Jersey.

22. This Court has personal jurisdiction over DRL at least because, upon information and belief, if the DRL ANDA is approved, the DRL ANDA Products will be marketed and distributed by Dr. Reddy's Laboratories, Inc., purportedly at the direction and control of Dr. Reddy's Laboratories, Ltd., in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey. Specifically, upon information and belief, if DRL succeeds in obtaining FDA approval, DRL will sell the DRL ANDA Products in the State of New Jersey.

23. Upon information and belief, Dr. Reddy's Laboratories, Ltd. intends to benefit directly if the DRL ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of the DRL ANDA.

24. Upon information and belief, Dr. Reddy's Laboratories, Inc. intends to benefit directly if the DRL ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of the DRL ANDA.

25. Upon information and belief, Dr. Reddy's Laboratories, Inc. acts at the direction, and for the benefit, of Dr. Reddy's Laboratories, Ltd. and is controlled and/or dominated by Dr. Reddy's Laboratories, Ltd.

26. Upon information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. act, operate, and/or hold themselves out to the public as a single integrated business.

27. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Dr. Reddy's Laboratories, Inc. has a principal place of business in New Jersey and has and will continue to engage in infringing activities in New Jersey.

28. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Dr. Reddy's Laboratories, Ltd. is incorporated in India and may be sued in any judicial district in which the Defendant is subject to the court's personal jurisdiction.

29. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b). DRL has previously consented to venue in this Judicial District.[9]

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[9] *See, e.g.*, *Celgene Corp. v. Dr. Reddy's Labs., Ltd.*, No. 21-2111 (D.N.J. Apr. 23, 2021), ECF No. 10 (showing that DRL filed a counterclaim and did not contest personal jurisdiction); *Horizon Pharma, Inc. v. Dr. Reddy's Labs., Ltd.*, No. 15-3324 (D.N.J. Feb. 19, 2016), ECF No. 28 (showing that DRL admitted to personal jurisdiction).

FACTS AS TO ALL COUNTS

30. Supernus's Trokendi XR® is sold and marketed under New Drug Application ("NDA") No. 201635, which was approved by the FDA for the manufacture and sale of topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg.

31. Trokendi XR® is an antiepileptic drug indicated: (i) as an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; (ii) as an adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and (iii) for the preventive treatment of migraine in patients 12 years of age and older.

32. Trokendi XR®'s recommended dosage: (i) for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily, and in patients 6 to 9 years of age is based on weight; (ii) for adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut syndrome is 200 mg to 400 mg orally once daily and with primary generalized tonic-clonic seizures is 400 mg orally once daily, and for adjunctive therapy for patients 6 to 16 years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily; and (iii) for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

33. FDA's publication, titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book"), lists ten (10) patents, specifically the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents, as covering Supernus's Trokendi XR®. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), these ten

(10) patents were submitted to the FDA with or after the approval of NDA No. 201635. These ten (10) patents are listed in the Orange Book as covering Trokendi XR®.

34. The '576 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '576 patent.

35. The '580 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '580 patent.

36. The '683 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on March 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '683 patent.

37. The '248 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on November 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '248 patent.

38. The '191 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on November 18, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '191 patent.

39. The ’989 patent, titled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on March 31, 2015, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’989 patent.

40. The ’940 patent, titled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on January 24, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’940 patent.

41. The ’004 patent, titled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on January 31, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’004 patent.

42. The ’983 patent, titled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on April 18, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’983 patent.

43. The ’790 patent, titled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on June 11, 2019, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’790 patent.

44. Upon information and belief, the DRL ANDA is based upon Trokendi XR® (topiramate extended-release capsules), 25 mg, 50 mg, 100 mg, and 200 mg, as its reference listed drug.

45. Upon information and belief, the DRL ANDA Products are topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg.

46. Upon information and belief, the proposed prescribing information for the DRL ANDA Products includes a header titled "Indications and Usage" and states that the DRL ANDA Products are indicated: (i) as an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; (ii) as an adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and (iii) for the preventive treatment of migraine in patients 12 years of age and older.

47. Upon information and belief, the proposed prescribing information for the DRL ANDA Products includes a header titled "Dosage and Administration" and states that: (i) the recommended dose for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily, and dosing in patients 6 to 9 years of age is based on weight; (ii) the recommended total daily dose as adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut syndrome is 200 mg to 400 mg orally once daily and with primary generalized tonic-clonic seizures is 400 mg orally once daily, and the recommended total daily dose as adjunctive therapy for patients 6 to 16 years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily; and (iii) the recommended total daily dose as treatment for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

48. Upon information and belief, the proposed prescribing information for the DRL ANDA Products also states under the header "Dosage and Administration" that the DRL ANDA

Products can be taken without regard to meals, to swallow capsule whole and intact, and do not sprinkle on food, chew, or crush.

49. Upon information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. acted in concert to develop the DRL ANDA Products and/or seek approval from the FDA to sell the DRL ANDA Products throughout the United States, including within this Judicial District.

50. Upon information and belief, both Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. participated in the preparation and/or filing of the DRL ANDA.

51. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)-(ii).

52. Upon information and belief, as of the date of the June 9 Notice Letter, DRL was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

53. The June 9 Notice Letter does not include any noninfringement contentions for the '576 patent, the '580 patent, the '683 patent, the '191 patent, the '004 patent, and the '790

patent. The June 9 Notice Letter does not include any noninfringement contentions unique to claims 2-6, 8-20 of the '248 patent, claims 2-6 and 8-20 of the '989 patent, claims 2-6 and 8-20 of the '940 patent, and claims 2-5, 7-12, 14-23, and 25-30 of the '983 patent.

54. Supernus and DRL did not reach agreement on mutually acceptable terms for an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8). As of the filing of this Complaint, DRL has not produced the DRL ANDA to Supernus.

FIRST COUNT
(Defendants' Infringement of the '576 Patent)

55. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

56. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '576 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '576 patent is an act of infringement of the '576 patent by DRL of one or more claims of the '576 patent under 35 U.S.C. § 271(e)(2)(A).

57. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

58. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '576 patent under 35 U.S.C. § 271.

59. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '576 patent under 35 U.S.C. § 271.

60. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '576 patent do not comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

61. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '576 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

62. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

SECOND COUNT
(Defendants' Infringement of the '580 Patent)

63. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

64. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '580 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '580 patent is an act of infringement of the '580 patent by DRL of one or more claims of the '580 patent under 35 U.S.C. § 271(e)(2)(A).

65. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

66. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '580 patent under 35 U.S.C. § 271.

67. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '580 patent under 35 U.S.C. § 271.

68. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '580 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

69. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '580 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

70. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

THIRD COUNT
(Defendants' Infringement of the '683 Patent)

71. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

72. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '683 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '683 patent is an act of infringement of the '683 patent by DRL of one or more claims of the '683 patent under 35 U.S.C. § 271(e)(2)(A).

73. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

74. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '683 patent under 35 U.S.C. § 271.

75. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '683 patent under 35 U.S.C. § 271.

76. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '683 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

77. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '683 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

78. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

FOURTH COUNT
(Defendants' Infringement of the '248 Patent)

79. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

80. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '248 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '248 patent is an act of infringement of the '248 patent by DRL of one or more claims of the '248 patent under 35 U.S.C. § 271(e)(2)(A).

81. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

82. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '248 patent under 35 U.S.C. § 271.

83. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '248 patent under 35 U.S.C. § 271.

84. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '248 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

85. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '248 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

86. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

FIFTH COUNT
(Defendants' Infringement of the '191 Patent)

87. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

88. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '191 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '191 patent is an act of infringement of the '191 patent by DRL of one or more claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A).

89. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

90. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '191 patent under 35 U.S.C. § 271.

91. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '191 patent under 35 U.S.C. § 271.

92. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '191 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

93. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '191 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

94. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

SIXTH COUNT
(Defendants' Infringement of the '989 Patent)

95. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

96. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '989 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United

States of the DRL ANDA Products before the expiration of the '989 patent is an act of infringement of the '989 patent by DRL of one or more claims of the '989 patent under 35 U.S.C. § 271(e)(2)(A).

97. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

98. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '989 patent under 35 U.S.C. § 271.

99. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '989 patent under 35 U.S.C. § 271.

100. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '989 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

101. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '989 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

102. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

SEVENTH COUNT
(Defendants' Infringement of the '940 Patent)

103. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

104. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '940 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '940 patent is an act of infringement of the '940 patent by DRL of one or more claims of the '940 patent under 35 U.S.C. § 271(e)(2)(A).

105. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

106. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '940 patent under 35 U.S.C. § 271.

107. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '940 patent under 35 U.S.C. § 271.

108. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '940 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

109. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '940 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

110. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

EIGHTH COUNT
(Defendants' Infringement of the '004 Patent)

111. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

112. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '004 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '004 patent is an act of infringement of the '004 patent by DRL of one or more claims of the '004 patent under 35 U.S.C. § 271(e)(2)(A).

113. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

114. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '004 patent under 35 U.S.C. § 271.

115. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '004 patent under 35 U.S.C. § 271.

116. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '004 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

117. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '004 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

118. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

NINTH COUNT
(Defendants' Infringement of the '983 Patent)

119. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

120. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '983 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '983 patent is an act of infringement of the '983 patent by DRL of one or more claims of the '983 patent under 35 U.S.C. § 271(e)(2)(A).

121. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

122. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '983 patent under 35 U.S.C. § 271.

123. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '983 patent under 35 U.S.C. § 271.

124. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '983 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

125. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '983 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

126. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

TENTH COUNT
(Defendants' Infringement of the '790 Patent)

127. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

128. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '790 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '790 patent is an act of infringement of the '790 patent by DRL of one or more claims of the '790 patent under 35 U.S.C. § 271(e)(2)(A).

129. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

130. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '790 patent under 35 U.S.C. § 271.

131. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '790 patent under 35 U.S.C. § 271.

132. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '790 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

133. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '790 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

134. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Supernus respectfully requests the following relief:

i. A Judgment declaring that the patents-in-suit are valid and enforceable;

ii. A Judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that the submission to FDA and filing of ANDA No. 217231 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products was an act of infringement of the patents-in-suit by Defendants;

iii. A Judgment pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the DRL ANDA Products before the expiration of the patents-in-suit (including any regulatory extensions) would directly and/or indirectly infringe the patents-in-suit;

iv. An Order, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, that the effective date of any approval of the DRL ANDA Products shall be no earlier than the date on which the patents-in-suit expire (including any regulatory extensions);

v. An Order, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and any person in active concert or participation or privity with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the

United States, and/or importation in the United States of the DRL ANDA Products until the expiration of the patents-in-suit (including any regulatory extensions);

vi. A Judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, awarding Supernus damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217231 that infringes the patents-in-suit;

vii. A Judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, declaring that Defendants' infringement of the patents-in-suit is willful and awarding Supernus enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217231 that infringes the patents-in-suit (including any regulatory extensions);

viii. A Judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Supernus its attorneys' fees and costs; and

ix. Such other and further relief as this Court may deem just and proper.

Dated: July 22, 2022

By: s/ William C. Baton

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that the matter in controversy involves the same plaintiff, same drug product, and same patents that are at issue in the matters captioned *Supernus Pharmaceuticals, Inc. v. Ajanta Pharma Ltd.*, C.A. No. 21-6964 (GC)(LHG) (D.N.J.) (consolidated), *Supernus Pharmaceuticals, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, C.A. No. 21-17104 (FLW)(LHG) (D.N.J.), *Supernus Pharmaceuticals, Inc. v. Lupin Limited*, C.A. No. 21-1293 (MN) (D. Del.), and *Supernus Pharmaceuticals, Inc. v. Alkem Laboratories Ltd.*, C.A. No. 22-3511 (EEB)(SRH) (N.D. Ill.).

To the best of my knowledge, this matter is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: July 22, 2022

By: s/ William C. Baton

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